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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,978	11/26/2001	Yun-Peng Huang	33154-176173	5332

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EXAMINER

YOUNG, JOSEPHINE

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/991,978

Applicant(s)

HUANG ET AL.

Examiner

Josephine Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Specification*

The disclosure is objected to because of the following informalities: The specification is replete with grammatical errors.

Further, on page 6, lines 19-20 and page 7, lines 1-2, the specification indicates that  $A^+$ , which appears to be monovalent, can also be  $Ca^{++}$ . It is unclear as to how the appropriate valence for the radical can be achieved when  $A^+$  is  $Ca^{++}$ .

On page 10, line 17, it is unclear as to how the diagram illustrates how a starch or cellulose based excipient reacts with the water-absorbing radical to form the methoxy-acetate sodium linkage as it appears as though only the product of the reaction was depicted.

On page 12, lines 1-8, the specification attempts to compare the residual solvent concentration in commercially available excipients and Yung-Zip's DZP®, a modified sodium starch glycolate prepared according to the present residue extraction method. However it is unclear as to which method is being referred as several extraction methods are disclosed. Further, it is unclear as to how DZP® compares to the commercially available excipients, as only Yung-Zip's DST® and DSF® excipients are in Table 3.

The use of the trademarks EXPLTAB®, PRIMOJEL®, TABLO®, VIVASTAR®, DST®, DSF® and DZP® have been noted in this application. It is noted that while the marks are capitalized wherever they appear, they are not accompanied by generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

adjust to  
compliance  
w/ 1.126  
first paragraph to  
renumber claim  
1-28  
in ch 6-17  
renumber  
claim 28.

Appropriate correction is required.

#### *Claim Objections*

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

There are two claim 21's. Therefore, the first claim 21 has been renumbered claim 27. The claims cited herein are referenced accordingly.

#### *Claim Rejections - 35 USC § 112, First Paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

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The instant claims recite low-residual-solvent excipients with a residual solvent content of less than 3000 ppm.

The specification disclosure does not sufficiently teach any excipient which exhibits the necessary properties commiserate with the scope of the claims.

The specification is directed to low-residual-solvent excipients and methods to manufacture polysaccharides conjugated to  $-\text{CH}_2\text{COONa}$ , a water-absorbing compound. The specification then discloses that these conjugated polysaccharides can be washed with methanol/water, isopropanol/water or acetone/water to produce a low-residual-solvent excipient. However, the specification does not teach if any or all of these excipients meet the limitations of the claims, i.e. have a residual solvent content of less than 3000 ppm.

With regard to the description requirement, a showing of sufficient identifying characteristics is necessary to demonstrate possession of the claimed generic(s).

In the present instance, the claimed invention contains no identifying characteristics for the excipients to indicate that they have a residual solvent content of less than 3000 ppm. The specification disclosure clearly does not teach the scope of the low-residual-solvent excipients of the presently claimed invention.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "water absorbing property" renders the claims in which it appears indefinite. In the absence of the specific modification to the excipient or distinct language to describe the structural modifications or the chemical names of the excipient of this invention, the identity of said property would be difficult to describe and the metes and bounds of said excipient comprising water absorbing property Applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. It is unclear as to what the structural modification of the excipient would be to obtain this water absorbing property when it is not limited to modification with the water-absorbing radical of formula  $-RCOO^-A^+$  of claim 9.

With regard to claims 9, 21 and 23-24, it is unclear as to how  $A^+$ , which appears to be monovalent, can also be divalent  $Ca^{++}$ . Further, it is unclear as to how the appropriate valence for the radical can be achieved when  $A^+$  is  $Ca^{++}$ .

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over patent US 5,478,571 to GALA et al. (A) in view of patent US 5,840,329 to BAI (B).

Applicant claims low-residual-solvent excipients comprising water-absorbing property, for instance a polysaccharide with a water-absorbing radical of formula  $-R-COO^-A^+$ . Applicant also claims methods for obtaining said low-residual-solvent excipients by mixing a solvent/water solution with said low-residual-solvent excipient, and removing the solvent via filtration and drying. Applicant claims various particular polysaccharides. In addition, Applicant claims various solvent ratios and reaction conditions.

GALA teaches methods to remove residual solvent alcohols without adverse affects to the drug by adding a small amount of water (col. 2, lines 24-30). In particular, in col. 3, lines 45-57, GALA teaches that when the solvent content has been reduced to about 20% to 1.5% w/w of the original amount, approximately 0.1% to about 5.0% water is added to the system until all the solvent is removed. GALA discloses that the excipient blend of conventional carrier materials can be lactose, microcrystalline cellulose and cornstarch (col. 3, lines 28-33). In addition GALA discloses that the solvent can be an alcohol, such as ethanol, methanol or a blend of methanol and ethanol (col. 3, lines 33-36).

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GALA does not specifically disclose each of the particular polysaccharides claimed not does GALA disclose that the excipient can be one with water-absorbing properties. Further, GALA does not explicitly teach that the solvent can be acetone. Finally, GALA may not teach each of the various solvent ratios or reaction conditions.

BAI teaches that various polysaccharides, including acylated polysaccharides, are well known in the art to be suitable excipients. See col. 8, lines 12-39. In particular, BAI teaches that carboxymethylcellulose and sodium starch glycolate, polysaccharides with water-absorbing properties, are known as inert pharmaceutical excipients.

It would have been obvious to one of ordinary skill in the art to use the method of GALA to reduce the residual solvent content of any known drug/excipient system. Therefore, a skilled artisan would have been motivated and would have had a reasonable expectation of success to use any known conventional excipient, such as carboxymethylcellulose and sodium starch glycolate, which are acylated and thus have the disclosed water-absorbing properties, as taught by BAI, in the method provided by GALA to obtain the low-residual-solvent excipient claimed in the present invention. Further, the choice of solvent and reaction conditions, i.e. temperature and agitation methods, are seen to be a choice of experimental design, are well known to one of ordinary skill and are well within the purview of the prior art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out



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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Conclusion***

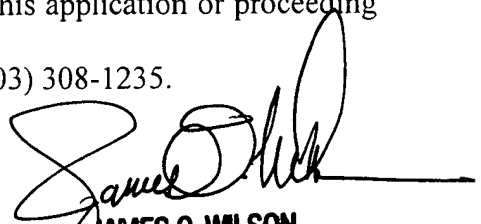
Claims 1-27 are pending. Claim 21 is objected to. Claims 1-27 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY  
January 13, 2003

  
**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**